NOV - 4 2011

11. 510(k) Summary according to 807.92(c) & Executive Summary

Submitted by:
ACES GmbH
Ludwigstr. 26
70794 Filderstadt, Germany

Contact:
Frank T. Trautwein, Principal & Managing Director
Tel.: +49 (711) 787 4162
Email: ft@acesgmbh.de

Trade Name:	FXA™
Regulation Name:	Picture archiving and communication system
Regulation Number:	21 CFR §892.2050,
Regulatory Class:	II
Product Code:	90 LLZ

Intended Use:
The FXA™ software is a quantitative imaging software application. It is designed for physicians and clinical professions who are interested in the analysis of motion in medical images, particularly in musculoskeletal images. The FXA™ software permits users to review static and dynamic digital images acquired from a variety of radiographic sources for the purpose of facilitating a quantitative assessment of relative motion. Information about the motion of selected objects, such as bone structures, can be generated and presented in the form of a report containing graphics, charts, text and statistical data.

Device Description:
The FXA™ software is a software tool which was developed to measure static dimensions and to analyze relative motion of implants or bony structures. Basis for the analysis are medical images such as functional radiographs. The FXA™ software was developed with the aim to detect and analyze even small changes with high precision, high reproducibility and low operator variability. For this, patent-pending algorithms were developed and implemented for image-superimposition and the automatic detection of bony structures within selected areas of the image. The software may be installed on workstations with Windows® operating system according to the software requirement specification (SRS, (Attachment B01)).

Predicate Device(s):
The selected predicate device is the QMA™ software by Medical Metrics Inc. (K022585).

Summary of Characteristic Performance Data:
The predicate device and the FXA™ software have been tested and characterized in various tests:

1) Tests under "best case" conditions, with the aim to exclude artifacts related to image acquisition or image quality (Attachment F01)
2) Tests under real conditions
   a. Through images obtained from in-vitro cadaver experiments (Attachment I)
   b. Through side-by-side comparison with real clinical images (Attachment H)
3) Tests addressing the inter- and intra-observer variability (Attachment F04)

The test results can be summarized in the table below:

Measurement Error for Range of Motion measurements mean ± standard deviation *(reported absolute amount of error for predicate)*	FXA™	QMA™
1) Ideal Conditions	-0.01° ± 0.03°	0.00° ± 0.10° *(0.08° ± 0.06°)*
2a) Cadaver Experiment	0.04° ± 0.13°	0.00° ± 0.53° *(0.47° ± 0.24°)*
3) Inter-observer Variability	0.00° ± 0.06°	0.00° ± 1.29° *(0.88° ± 0.85°)*

The data presented demonstrates that the FXA™ software is adequate to facilitate highly accurate motion analysis within radiographic images. In all tests, the accuracy of the FXA™ software was higher than that of the predicate device.
Both, FXA™ and QMA™ products are designed to be executed under the Windows® operating system and PC hardware and are to be operated by qualified personnel only. The FXA™ and QMA™ products share the same conceptual technology of motion quantification through software assisted superimpositioning of medical images, and thus have the same potential error sources and analysis capabilities.

In conclusion, the FXA™ software is as safe, as effective, and performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES · Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Frank T. Trautwein
Principal & Managing Director
ACES Ing.-GmbH
Ludwigstr. 26
Filderstadt, BW, 70794
GERMANY

NOV - 4 2011

Re: K110765
Trade/Device Name: FXA™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 9, 2011
Received: September 12, 2011

Dear Mr. Trautwein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number: K110765

Device Name: FXA™

Indications for Use:

The FXA™ software is a quantitative imaging software application. It is designed for physicians and clinical professionals who are interested in the analysis of motion in medical images, particularly in musculoskeletal images. The FXA™ software permits users to review static and dynamic digital images acquired from a variety of radiographic sources for the purpose of facilitating a quantitative assessment of relative motion and static measurement parameters. Information about the motion of selected objects, such as bone structures, can be generated and presented in the form of a report containing graphics, charts, text and statistical data.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Patel

Division Sign-Off Office of
In Vitro Diagnostic Device
Evaluation and Safety
510(k) K110765